

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* ZHENG J. LI and ANDREW V. TRASK

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Appeal 2007-1348  
Application 10/650,253  
Technology Center 1600

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Oral Argument: None  
Decided: 01 May 2007

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*Before:* FRED E. McKELVEY, *Senior Administrative Patent Judge*, and ROMULO H. DELMENDO and SALLY GARDNER LANE, *Administrative Patent Judges*.

McKELVEY, *Senior Administrative Patent Judge*.

DECISION ON APPEAL

1           **A. Statement of the case**

2           This *ex parte* appeal under 35 U.S.C. § 134(a) is from rejections of  
3 claims 125 and 128-144.

4           We have jurisdiction under 35 U.S.C. § 6(b).

5           The application on appeal was filed on 27 August 2003.

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1       The application on appeal is said to be a continuation of application  
2 10/152,106, filed 21 May 2002, which claims benefit of (1) provisional  
3 application 60/343,041, filed 21 December 2001, (2) provisional application  
4 60/297,741, filed 12 June 2001, and (3) provisional application 60/292,565,  
5 filed 22 May 2001.

6       The real party in interest is Pfizer Inc.

7       The Examiner rejected claims 125 and 128-144 for failure to comply  
8 with the enablement requirement of the first paragraph of 35 U.S.C. § 112.

9       The Examiner further rejected claims 125 and 128-144 as being  
10 anticipated under 35 U.S.C. § 102(b), alternatively as being unpatentable  
11 under 35 U.S.C. § 103(a), over Bright.

12       The Examiner still further rejected claims 125 and 128-144 as being  
13 unpatentable under 35 U.S.C. § 103(a) over Singer and Curatolo. (The  
14 reader should know that no references to *et al.* are made in this opinion.)

15       The following references were relied upon by the Examiner.

	<u>Name</u>	<u>Patent Number</u>	<u>Issue Date</u>
17	Bright	US 4,474,768	02 Oct. 1984
18	Curatolo	US 5,605,889	25 Feb. 1997
19	Singer	US 6,365,574 B2	02 Apr. 2002

20  
21       Bright and Curatolo are prior art vis-à-vis appellants under 35 U.S.C.  
22 § 102(b).

23       Singer is facially prior art vis-à-vis appellants under 35 U.S.C.  
24 § 102(e). Appellants have abandoned any attempt to antedate Singer.  
25 Supplemental Reply Brief, filed 16 October 2006.

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1           **B. Record on appeal**

2           1. Specification, including original claims and a preliminary  
3 amendment to the specification setting out the claimed priority.  
4           2. Drawings  
5           3. Final Rejection entered 16 March 2006  
6           4. Brief on Appeal filed 03 August 2006  
7           5. Examiner's Answer entered 31 August 2006  
8           6. Reply Brief filed 13 September 2006  
9           7. Examiner's notation of Reply Brief entered 03 October 2006  
10          8. Supplemental Reply Brief filed 16 October 2006 (in which  
11 appellants explicitly withdraw reliance on a Rule 131 declaration of  
12 Dr. Richard Todd Darrington seeking to antedate Singer)  
13          9. Bright  
14          10. Curatolo  
15          11. Singer  
16          12. Memorandum Opinion and Order (Decision on Motions) entered  
17 in *Li v. Singer*, Interference 105,366, Paper 71 (Bd. Pat. App. & Int. Nov. 8,  
18 2006)—a copy of the Memorandum Opinion and Order appears in the  
19 evidence appendix of the Appeal Brief.

20  
21           **C. Issues**

22          There are three principal issues on appeal.

23          The first issue is whether appellants have sustained their burden of  
24 showing that the Examiner erred in rejecting the claims on appeal under  
25 35 U.S.C. § 112, first paragraph, for lack of an enabling description.

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1       The second issue is whether appellants have sustained their burden of  
2 showing that the Examiner erred in rejecting the claims on appeal as being  
3 anticipated under 35 U.S.C. § 102(b) by Bright, alternatively that the  
4 claimed subject matter is unpatentable under 35 U.S.C. § 103(a) over Bright.

5       The third issue is whether appellants have sustained their burden of  
6 showing that the Examiner erred in rejecting the claims on appeal as being  
7 unpatentable under 35 U.S.C. § 103(a) over Singer and Curatolo.

8       Involved in the resolution of all three issues is the scope of claim 125.  
9

10      **D. Findings of fact**

11      The following findings of fact are believed to be supported by a  
12 preponderance of the evidence. To the extent that a finding of fact is a  
13 conclusion of law, it may be treated as such. Additional findings as  
14 necessary may appear in the Discussion portion of the opinion.

15                  Claim 125

16      Claim 125 is representative of the claims on appeal.

17      According to the claims appendix accompanying the Appeal Brief,  
18 claim 125 reads [matter in brackets added]:

19                   A pharmaceutical dosage form comprising said [sic “a”]  
20                   [1] substantially pure crystalline azithromycin monohydrate  
21                   hemi-ethanol solvate and [2] a pharmaceutically acceptable  
22                   carrier or diluent; wherein said crystalline azithromycin  
23                   monohydrate hemi-ethanol solvate is characterized as having a  
24                   <sup>13</sup>C solid state NMR spectrum comprising at least one peak with  
25                   chemical shift of about 179.5 ppm.

## The invention

2 A review of the specification will reveal that the crystalline  
3 azithromycin to which appellants make reference in claim 125 is what we  
4 believe appellants call "substantially pure" azithromycin "Form F."

5 According to the specification, the invention relates to a crystal form  
6 of azithromycin where the crystal form is selected from forms C, D, E, F, G,  
7 H, J, M, N, O, P, Q and R. Specification, page 2:7-8.

8           A reference to Form F *per se* needs to be distinguished from a  
9       reference to “substantially pure” Form F vis-à-vis other possible Form F’s.  
10      See specification, page 2:28 and page 5:22-29.

11 The empirical formula of Form F is:



13 in the single crystal structure and is referred to by appellants as being  
14 azithromycin monohydrate hemi-ethanol solvate.

15 The structural formula of azithromycin itself is shown in the  
16 specification at page 1:8.

Form F has a  $^{13}\text{C}$  solid state NMR spectrum comprising at least one peak with chemical shift at about 179.5 ppm  $\pm$  0.2 ppm. Specification, page 2:19 and Fig. 23 (mentioned in the specification, page 9:6).

20 Crystallographic data of Form F is set out in a table on page 11 of the  
21 specification.

22 For further information concerning substantially pure azithromycin  
23 Form F we refer the reader to a MEMORANDUM OPINION and ORDER  
24 (Decision on Motions) entered in *Li v. Singer*, Interference 105,366,  
25 Paper 71 (Bd. Pat. App. & Int. Nov. 8, 2006).

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Claim 125 requires two ingredients: (1) substantially pure crystalline azithromycin Form F and (2) a carrier or diluent.

With respect to carriers and diluents, the following appears in the specification (page 32:25-33; emphasis added):

The active compound may be administered alone or in combination with pharmaceutically acceptable *carriers* or *diluents* ... and such administration may be carried out in single or multiple doses. More particularly, the active compound may be administered in a wide variety of different dosage forms, i.e., they may be combined with various pharmaceutically acceptable insert *carriers* in the form of tablets, capsules, lozenges, trouches, hard candies, powders, sprays, creams, salves, suppositories, jellies, gels, pastes, lotions, ointments, sachets, powders for oral suspension, *aqueous suspensions*, injectable solutions, elixirs, syrups, and the like. Such *carriers* include solid *diluents* or fillers, sterile aqueous media and various non-toxic organic solvents, etc.

Bright

20 Bright describes azithromycin. Col. 1, lines 16-17 and col. 2,  
21 lines 1-15.

22 Bright does not describe azithromycin Form F or substantially pure  
23 Form F.

Singer

25 Singer describes an azithromycin which Singer characterizes as an  
26 ethanolate of azithromycin having an ethanol content of about 1.5% to  
27 about 3%. Col. 4, lines 16-17 (claim 1).

Li has previously sustained its burden of establishing that a Singer ethanolate of azithromycin having an ethanol content of about 1.5% to about

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<sup>1</sup> 3% is not the same as substantially pure azithromycin Form F. *Li v. Singer*,  
<sup>2</sup> Interference 105,366, Paper 71 (Bd. Pat. App. & Int. Nov. 8, 2007).

Curatolo

4 We find it unnecessary to discuss what is described by Curatolo.

5

#### **E. Principles of law**

7       Claims undergoing examination are given their broadest *reasonable*  
8 construction *consistent with the specification*. *Burlington Industries v.*  
9 *Quigg*, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987);  
10      *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA  
11      1969).

12 During the examination of a patent application, an examiner has an  
13 initial burden of establishing some objective basis for questioning  
14 enablement of a specification. *In re Marzocchi*, 439 F.2d 220, 169 USPQ  
15 367 (CCPA 1971). On appeal from a lack of enablement rejection, the  
16 appellant bears the burden of showing that the examiner did not have a  
17 sufficient objective basis to legally support the rejection.

18 The fact that a claim may include inoperative embodiments does not  
19 *per se* render the claim unpatentable under the first paragraph of 35 U.S.C.  
20 § 112. *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976).

21 An anticipation under 35 U.S.C. § 102(b) or 102(e) requires a prior art  
22 reference to describe every limitation in a claim—either explicitly or  
23 inherently. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431  
24 (Fed. Cir. 1997).

1       A claimed invention is patentable if the subject matter of the claimed  
2 invention would not have been obvious to a person having ordinary skill in  
3 the art. 35 U.S.C. § 103(a); *Graham v. John Deere Co. of Kansas City*, 383  
4 U.S. 1 (1966).

5       Facts relevant to a determination of obviousness include (1) the scope  
6 and content of the prior art, (2) any differences between the claimed  
7 invention and the prior art, (3) the level of skill in the art and (4) any  
8 relevant objective evidence of obviousness or non-obviousness. *Graham*,  
9 383 U.S. at 17-18.

10  
11       **F. Discussion**

12               Lack of enablement and anticipation based on Bright

13       In this particular appeal, the lack of enablement rejection and the  
14 anticipation rejection based on Bright may be considered together.

15       Resolution of both rejections turns on a proper interpretation of  
16 claim 125.

17       The Examiner determined that there was a lack of enablement and an  
18 anticipation by Bright based on her finding that a crystalline compound  
19 cannot maintain its crystalline structure in an aqueous media. Examiner's  
20 Answer, page 3.

21       The Examiner also determined that appellants' "carrier" or "diluent"  
22 could be "sterile aqueous media." Examiner's Answer, page 3.

23       Since a crystalline compound cannot maintain its crystalline structure  
24 in water, the Examiner reasoned that appellants' disclosure is insufficient to  
25 enable one to make a combination of substantially pure Form F and water

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1 because on placing the substantially pure Form F in water there no longer  
2 would be any Form F. Examiner's Answer, page 3.

3       Using similar reasoning, the Examiner found that when substantially  
4 pure Form F is placed in water, a mixture of the azithromycin and water of  
5 appellants would be the same as a mixture of the azithromycin of Bright and  
6 water. Examiner's Answer, pages 4-5.

7       We agree with appellants, however, that claim 125 requires the  
8 presence of substantially pure azithromycin Form F.

9       To the extent that a mixture does not contain substantially pure  
10 Form F, it cannot fall within the scope of claim 125.

11       We can assume, as did the Examiner, that substantially pure Form F  
12 would not maintain its crystalline structure in water.

13       A mixture of (1) azithromycin, resulting from de-crystallization of  
14 Form F when placed in water, and (2) water are not covered by, and do not  
15 fall within the scope of claim 125.

16       Even if we assume that some embodiments within the scope of  
17 claim 125 might be non-enabled, the composition defined by claim 125  
18 would still be useful and the specification otherwise advises one skilled in  
19 the art how to make and use substantially pure azithromycin Form F mixed  
20 with other carriers and diluents. *In re Angstadt, supra.*

21       Bright does not describe a mixture containing substantially pure  
22 azithromycin Form F.

23       Accordingly, Bright cannot describe a mixture within the scope of  
24 claim 125.

25

1                           Obviousness based on Singer

2                           Singer, like Bright, does not describe or render obvious substantially  
3                           pure azithromycin Form F.

4                           Appellants and the Examiner agree that Curatolo likewise does not  
5                           describe substantially pure azithromycin Form F.

6                           Based on *Li v. Singer*, what surfaces in this case is that an essential  
7                           element of appellants' mixture does not appear in the prior art relied upon by  
8                           the Examiner.

9                           Accordingly, the scope and content of the prior art is such that the  
10                          prior art, as a whole, cannot render obvious the subject matter of claim 125.

11                           Additional observations

13                          1.        In fairness to the Examiner, we wish to point out that the Examiner's  
14                          Answer was entered on 31 August 2006, but our decision in *Li v. Singer* was  
15                          not entered until 08 November 2006.

16                          When the Examiner's Answer was written in August, the Examiner  
17                          could not have known what we might hold in November in an *inter partes*  
18                          case involving Li (one appellant here) and Singer (the reference relied upon  
19                          by the Examiner here).

20                          In *Li v. Singer*, Li was able to sustain its burden of showing that  
21                          Singer did not anticipate or render obvious subject matter which is  
22                          somewhat broader than the subject matter of claim 125.

23                          Had the Examiner been aware of *Li v. Singer*, we are confident the  
24                          rejection based on obviousness would not have been maintained.

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1    2. In the appeal brief an elaborate argument is made to the effect that the  
2    Examiner failed to follow PTO standards for claim construction. Appeal  
3    Brief, pages 10-12.

4                 In particular, it is said that the Examiner's claim interpretation in this  
5    case is inconsistent with claim interpretation by (1) the Examiner in other  
6    cases and (2) other examiners in other cases.

7                 The Examiner did not address appellants' argument and we think  
8    correctly so. The argument simply is irrelevant.

9                 Our appellate reviewing court, as well as other earlier reviewing  
10   courts, has made it clear for a long time that the issue in a case is whether an  
11   examiner and the board erred in the case under consideration. *In re Phillips*,  
12   315 F.2d 943, 137 USPQ 369 (CCPA 1963) (issuance of patent to third  
13   party is irrelevant to patentability on direct appeal in other case even if  
14   references are the same); *In re Riddle*, 438 F.2d 618, 169 USPQ 45 (CCPA  
15   1971) (an examiner's allowance of claim in patent does not bar rejection of  
16   claim in application to substantially same invention on substantially same art  
17   considered in patent prosecution). *See also Fessenden v. Coe*, 99 F.2d 426,  
18   38 USPQ 516 (D.C. Cir. 1938).

19                 We have given no consideration to appellants' argument concerning  
20   alleged different interpretation by the Examiner or other examiners in other  
21   cases.

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#### **G. Conclusions of law**

2 Appellants have sustained their burden on appeal of showing that the  
3 Examiner erred in rejecting claims 125 and 128-144 as being based on a lack  
4 of enablement under the first paragraph of 35 U.S.C. § 112.

5 Appellants have sustained their burden on appeal of showing that the  
6 Examiner erred in rejecting claims 125 and 128-144 as being anticipated  
7 under 35 U.S.C. § 102(b) by Bright.

8 Appellants have sustained their burden on appeal of showing that the  
9 Examiner erred in rejecting claims 125 and 128-144 as being unpatentable  
10 under 35 U.S.C. § 103(a) over Singer and Curatolo.

## H. Decision

13 ORDERED that the decisions of the Examiner rejecting  
14 claims 125 and 128-144 (1) for lack of enablement, (2) as being anticipated  
15 by Bright, alternatively unpatentable under 35 U.S.C. § 103(a), and (3) as  
16 being unpatentable over Singer and Curatolo are *reversed*.

17 FURTHER ORDERED that no time period for taking any  
18 subsequent action in connection with this appeal may be extended under  
19 37 C.F.R. § 1.136(a)(1)(iv) (2006).

REVERSED

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mv

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